

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 2960/169WO	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2008/066994	International filing date (day/month/year) 13/06/2008	(Earliest) Priority Date (day/month/year) 13/06/2007
Applicant CONFORMIS, INC.		

This International search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International search report consists of a total of 7 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the International search was carried out on the basis of:

- ☒ the International application in the language in which it was filed
☐ a translation of the International application into _____, which is the language of a translation furnished for the purposes of International search (Rules 12.3(a) and 23.1(b))

b. ☒ This International search report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43.6b(a)).

c. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the International application, see Box No. I.

2. ☒ Certain claims were found unsearchable (See Box No. II)

3. ☒ Unity of invention is lacking (see Box No. III)

4. With regard to the title,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this International search report, submit comments to this Authority

6. With regard to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No. 1

- ☒ as suggested by the applicant
☐ as selected by this Authority, because the applicant failed to suggest a figure
☐ as selected by this Authority, because this figure better characterizes the invention

b. ☐ none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2008/066994

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/17

ADD. A61B19/00 A61B17/00 A61B17/15

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 337 901 A (BROC CHRISTIAN) 18 October 1989 (1989-10-18)	1-17, 19, 39-53, 60-64 18
Y	figure 6	
Y	WO 2004/049981 A (IMAGING THERAPEUTICS INC [US]; BEREZ AARON [US]; FITZ WOLFGANG [US]; L) 17 June 2004 (2004-06-17) paragraphs [0255], [0268], [0269]	18
X	DE 203 03 498 U1 (AESCULAP AG & CO KG [DE]) 3 July 2003 (2003-07-03) figure 1	1
P, X	WO 2007/092841 A (CONFORMIS INC [US]; LANG PHILIPP [US]; FITZ WOLFGANG [US]; BOJARSKI RA) 16 August 2007 (2007-08-16) figure 26W	1-19, 39-53, 60-64

-/--



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

C document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

G document member of the same patent family

Date of the actual completion of the international search

24 September 2008

Date of mailing of the international search report

19/02/2009

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel: (+31-70) 340-2200
Fax: (+31-70) 340-3016

Authorized officer

Fernández Arillo, J

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/066994

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2005/148843 A1 (ROOSE JEFFREY R [US]) 7 July 2005 (2005-07-07) paragraph [0001] -----	1

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 20-38, 65

The subject-matter of claims 20-38 and 65 relates to a method for treatment of the human body by surgery, since, in view of the description, it is clear that the surgical instrument is guided during a surgical operation (see also claim 22, which further includes the step of cutting the tissue). Therefore, pursuant to Rule 39.1(iv) PCT, the subject-matter of said claims has not been searched.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/066994

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 20-38, 65
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

see additional sheet(s)

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-19, 39-53, 60-64

a guide having a surface conforming to a patient's tissue for solving the problem of improving the attachment of the guide to said tissue.

2. claims: 54-59

a surgical tool comprising one insert and a template, including a guide.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2008/066994

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 0337901	A	18-10-1989	FR 2629339 A1	06-10-1989
WO 2004049981	A	17-06-2004	AU 2003293203 A1	23-06-2004
			CA 2505419 A1	17-06-2004
			CN 1729483 A	01-02-2006
			EP 1575460 A2	21-09-2005
			JP 2006510403 T	30-03-2006
			KR 20050084024 A	26-08-2005
			US 2004236424 A1	25-11-2004
DE 20303498	U1	03-07-2003	NONE	
WO 2007092841	A	16-08-2007	AU 2007212033 A1	16-08-2007
			CA 2641241 A1	16-08-2007
			EP 1981409 A2	22-10-2008
			US 2007198022 A1	23-08-2007
US 2005148843	A1	07-07-2005	NONE	

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

RECEIVED

MAR 06 2009

see form PCT/ISA/220

BROMBERG & SUNSTEIN LLP

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43b.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2008/066994

International filing date (day/month/year)
13.06.2008

Priority date (day/month/year)
13.06.2007

International Patent Classification (IPC) or both national classification and IPC
INV. A61B17/17
ADD. A61B19/00 A61B17/00 A61B17/15

Applicant
CONFORMIS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43b.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1b(s(b)) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
D-80598 Munich
Tel.: +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4485

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Fernández Arillo, J

Telephone No. +49 89 2399-8495



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2008/066994

Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☒ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ In electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2008/066994

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 20-38, 54-59, 65

because:

☒ the said international application, or the said claims Nos. 20-38, 65 relate to the following subject matter which does not require an international search (*specify*):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for the whole application or for said claims Nos. 20-38, 54-59, 65

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2008/066994

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA206) to pay additional fees, the applicant has, within the applicable time limit:
- ☐ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☒ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-19, 39-53, 60-64

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>18</u>
	No: Claims	<u>1-17, 19, 39-53, 60-64</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-19, 39-53, 60-64</u>
Industrial applicability (IA)	Yes: Claims	<u>1-19, 39-53, 60-64</u>
	No: Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2008/066994

Box No. VI Certain documents cited

1. Certain published documents (Rules 43*bis*.1 and 70.10)
and /or
2. Non-written disclosures (Rules 43*bis*.1 and 70.9)
see form 210

1.- Reference is made to the following documents:

D1: EP0337901 A 19891018

D2: WO2004049981 A 20040617

2.- Re Item III.

The subject-matter of **claims 20-38 and 65** relates to a method for treatment of the human body by surgery, since, in view of the description, it is clear that the surgical instrument is guided during a surgical operation (see also claim 22, which further includes the step of cutting the tissue). Therefore, pursuant to Rule 39.1(iv) PCT, the subject-matter of said claims has not been searched.

3.- Re Item IV

This Authority considers that there are 2 groups of potential inventions covered by the claims indicated as follows:

I: **Claims 1-19, 39-53, 60-64** directed to a guide having a surface conforming to a patient's tissue for solving the problem of improving the attachment of the guide to said tissue.

II: **Claims 54-59** directed to a surgical tool comprising one insert and a template including a guide.

The only **common technical feature** linking together both groups of potential inventions is **the presence of a surgical guide**, which is, obviously, a well-known feature and **cannot** be considered to be **special** in the sense of Rule 13.2 PCT. The two groups of potential inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, since they are not linked by common or corresponding **special** technical features (Rule 13.2 PCT). Thus, the present application lacks unity "a priori", that is, before considering the claims in relation with any prior art (see Guidelines PCT/GL/ISPE/1,

10.03).

4.- Re Item V.

4.1 Clarity

The subject-matter of **claim 1** is not clear in the sense of Article 6 PCT, since the "contact surface" of the third line and the "stop" of the last paragraph are both defined with respect to the patient, who is not part of the claimed guide. It is also not clear, how the stop is based on patient specific information. Furthermore it is to be noted that this definition, as far as it could be understood, does not restrict the scope the claim, since there can be found for any guide of the prior art a patient to whom said guide is specifically adapted.

The same objection applies to **claims 6, 7 to 10, 12, 39, 40, 41, 44, 45, 48, 49, 52, 53, 60, 62, 63 and 64**.

4.2 Novelty

4.2.1 The subject-matter of **claim 1** is not new in the sense of **Article 33(2) PCT**, since D1 (see D1, fig. 6) discloses (the references in parentheses applying to D1):

A surgical cutting guide (7) for guiding a surgical instrument along a cutting path located on a biological tissue, the cutting guide comprising:
a contact surface that conforms (see fig. 6) to a surface associated with the tissue (see remark 4.1 above);
at least one guide (upper horizontal surface of 7) for restricting movement of a surgical instrument in a first direction and for allowing the movement of the surgical instrument in a second direction along a cutting path across the surface of the tissue; and
a stop (8, see also col. 4 l. 7-11) for restricting movement of the surgical instrument in the second direction along the cutting path (**claim 1**).

4.2.2 The subject-matter of **claims 2-17, 19, 39-53, 60-64** is not new in the sense of

Article 33(2) PCT, since D1 (see D1, fig. 6) further discloses the following features (the references in parentheses applying to D1):

the abutments of **claims 2 and 3** (see D1, fig. 6),
the contact of **claim 4** (see D1, fig. 6),
the tissue of **claim 6**,
the features of **claims 5, 7 to 10, 12, 39, 40, 44, 52, 53, 60, 62, 63 and 64** (see clarity objection 4.1 above),
the cutting plane of **claim 11**,
the stops (8) of **claims 13, 14, 15, 41, 45, 48, 49 and 61**
the features of **claim 16** (note that the surgical instrument is not part of the claimed guide),
the use (knee) of **claims 17, 42, 43, 46 and 47**,
the perpendicularity of **claim 19**, and
the attachments of **claims 50 and 51**.

4.3 Inventive step

The subject-matter of **claim 18** does not involve an inventive step in the sense of **Article 33(3) PCT**, since D2 (see D2 para. 255, 268 and 269) discloses a guide with a contact surface having a plurality of concavities and convexities for solving the same problem as the present application, namely, to better conform to the bone surface. The combination of D1 and D2 to come to a guide according to **claim 18** would therefore be obvious to the skilled person.

4.4 Further remarks

3.4.1 **Claims 1, 39, 40, 41, 45, 48, 49, 52, 54, 60 and 63** have been drafted as separate independent claims. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

3.4.2 It is to be noted that the guide of D2 is manufactured (see D2 para. 255, 268 and 269) in the same way as the one of the present application, namely, based on patient's specific information previously obtained, thereby solving the problem of providing a customized guide.

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

General information

For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.

Amending claims under Art. 19 PCT

Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.

Filing a demand for international preliminary examination

In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/ WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT).

If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).

Filing informal comments

After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.

End of the international phase

At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPER (international preliminary examination report).

Relevant PCT Rules and more information

Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, OJ 11/2003, OJ 12/2003